

Based on Application No. PCT/IE00/00060
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number of claims is 20, of which three claims are in independent form.

Please add the following claims.

20. A formulation according to Claim 1, wherein the core further comprises an organic acid, the SSRI component and the organic acid being present in a ratio of from 50:1 to 1:50.

21. A formulation according to Claim 1, wherein the SSRI is selected from citalopram, clomipramine, fluoxetine, fluvoxamine, paroxetine, sertraline, trazodone, venlafaxine and zimeldine or a pharmaceutically acceptable salt thereof.

22. A formulation according to Claim 21, wherein the SSRI is fluvoxamine or a pharmaceutically acceptable salt thereof.

23. A formulation according to claim 1, wherein the SSRI release rate from the particles when measured *in vitro* using a USP type II dissolution

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apparatus (paddle) according to US Pharmacopoeia
XXII in 0.05 M phosphate buffer at pH 6.8
substantially corresponds to the following
dissolution pattern:

- (a) no more than 15% of the total SSRI is released after 0.5 of an hour of measurement in said apparatus;
- (b) no more than the 25% of the total SSRI is released after 1 hour of measurement in said apparatus;
- (c) between 20% and 75% of the total SSRI is released after 2 hours of measurement in said apparatus;
- (d) not less than 75% of the total SSRI is released after 4 hours of measurement in said apparatus; and
- (e) not less than 85% of the total SSRI is released after 6 hours of measurement in said apparatus.

24. A formulation according to Claim 1, wherein the SSRI release rate from the particles when measured *in vitro* using a USP type II dissolution

apparatus (paddle) according to US Pharmacopoeia
XXII in 0.05 M phosphate buffer at pH 6.8
substantially corresponds to the following
dissolution pattern:

- Sup*
C3
cont.
- B*
- (a) no more than 20% of the total SSRI is released after 4 hours of measurement in said apparatus;
- (b) no more than 45% of the total SSRI is released after 6 hours of measurement in said apparatus;
- (c) between 45% and 80% of the total SSRI is released after 8 hours of measurement in said apparatus;
- (d) not less than 70% of the total SSRI is released after 10 hours of measurement in said apparatus; and
- (e) not less than 80% of the total SSRI is released after 12 hours of measurement in said apparatus.

25. A formulation according to Claim 1 in a form suitable for oral administration.

26. A formulation according to Claim 1 in a form suitable for oral administration and comprising a blend of said particles in admixture with an immediate release form of SSRI or a pharmaceutically acceptable salt thereof to ensure a rapid attainment of effective therapeutic blood levels.

27. A formulation according to Claim 26, wherein the immediate release form of SSRI comprises pellets.

28. A formulation according to Claim 25, wherein the SSRI release rate when measured *in vitro* using a USP type II dissolution apparatus (paddle) according to US Pharmacopoeia XXII in 0.05 M phosphate buffer at pH 6.8 substantially corresponds to the following dissolution pattern:

- (a) no more than 20% of the total SSRI is released after 1 hour of measurement in said apparatus;
- (b) no more than 60% of the total SSRI is released after 2 hours of measurement in said apparatus;

- Sup
C4
cont.
- BI
- (c) not less than 20% of the total SSRI is released after 4 hours of measurement in said apparatus;
- (d) not less than 35% of the total SSRI is released after 6 hours of measurement in said apparatus;
- (e) not less than 50% of the total SSRI is released after 8 hours of measurement in said apparatus;
- (f) not less than 70% of the total SSRI is released after 10 hours of measurement in said apparatus; and
- (g) not less than 75% of the total SSRI is released after 12 hours of measurement in said apparatus.

29. A formulation according to Claim 25, wherein the SSRI release rate when measured *in vitro* using a USP type II dissolution apparatus (paddle) according to US Pharmacopoeia XXII in 0.06 M phosphate buffer at pH 6.8 substantially corresponds to the following dissolution pattern:
- (a) no more than 20% of the total SSRI is

released after 1 hour of measurement in said apparatus;

(b) no more than 45% of the total SSRI is released after 2 hours of measurement in said apparatus;

(c) between 20% and 70% of the total SSRI is released after 4 hours of measurement in said apparatus;

(d) between 35% and 85% of the total SSRI is released after 6 hours of measurement in said apparatus;

(e) not less than 50% of the total SSRI is released after 8 hours of measurement in said apparatus;

(f) no less than 70% of the total SSRI is released after 10 hours of measurement in said apparatus; and

(g) not less than 75% of the total SSRI is released after 12 hours of measurement in said apparatus.

30. A formulation according to Claim 1, wherein the SSRI release rate when measured *in vitro* using a

Sub
C4
cont.

B1

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Sw
C4
cont.

USP type II dissolution apparatus (paddle)
according to US Pharmacopoeia XXII in 0.05 M
phosphate buffer at pH 6.8 substantially
corresponds to the following dissolution pattern:

- B1
- (a) no more than 50% of the total SSRI is
released after 2 hours of measurement in
said apparatus;
- (b) not less than 35% of the total SSRI is
released after 6 hours of measurement in
said apparatus; and
- (c) not less than 80% of the total SSRI is
released after 22 hours of measurement in
said apparatus.

31. A formulation according to Claim 4, wherein the
core further comprises an organic acid, the SSRI
component and the organic acid being present in a
ratio of from 50:1 to 1:50.
32. A formulation according to Claim 5, wherein the
core further comprises an organic acid, the SSRI
component and the organic acid being present in a
ratio of from 50:1 to 1:50.